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EXAMINER

NGUYEN, QUANG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STANTON L. GERSON

Appeal 2012-006722
Application 09/321,655
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 2-5 and 7 (App. Br. 2; Reply Br. 3). We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method for transforming hematopoietic progenitor cells to express a protein. Claim 5 is representative and is reproduced in the “CLAIMS APPENDIX” of Appellant’s Brief.

Claims 3-5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Nolta¹ as evidenced by Prockop² and/or ‘765.³

Claims 2, 4, and 5 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wells⁴ as evidenced by Prockop and/or ‘765.

Claims 5 and 7 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Nolta or Wells in combination with Prockop and Caplan.⁵

We reverse.

Nolta or Wells as evidence by Prockop and/or ‘765:

ISSUE

Does the preponderance of evidence on this record support Examiner’s finding that Nolta as evidenced by Prockop and/or ‘765 teaches Appellant’s claimed invention?

FACTUAL FINDINGS (FF)

FF 1. Human mesenchymal stem cells (hMSCs) “can be distinguished from the more complex cellular microenvironment present for example in the marrow stroma (‘Dexter stroma’). MSCs are distinct in morphology

¹ Jan A. Nolta, et al., *Analysis of Optimal Conditions for Retroviral-Mediated Transduction of Primitive Human Hematopoietic Cells*, 86(1) BLOOD 101-110 (1995).

² Darwin J. Prockop, *Marrow Stromal Cells as Stem Cells for Nonhematopoietic Tissues*, 276 SCIENCE 71-74 (1997).

³ Prockop et al., US 2002/0168765 A1, published November 14, 2002.

⁴ S. Wells, et al., *The presence of an autologous marrow stromal cell layer increases glucocerebrosidase gene transduction of long-term culture initiating cells (LTCICs) from the bone marrow of a patient with Gaucher disease*, 2(8) GENE THER. 512-20 (1995).

⁵ Caplan et al., US 5,486,359, issued January 23, 1996.

from Dexter stroma and also lack surface markers for T and B lymphocytes, macrophages and endothelial cells” (Spec. 5: 14-17).

FF 2. Nolta and Wells teach methods of transducing human CD34 cells in the presence of stromal cells (Ans. 5 and 7).

FF 3. Examiner finds that Nolta’s “stromal cell population . . . is devoid of most hematopoietic cells except for mature macrophages which comprised less than 1% of the culture” (Ans. 5 (emphasis removed)).

FF 4. Examiner finds that the bone marrow stromal cell population taught by Nolta and Wells inherently includes “mesenchymal stem cells or isolated multipotential bone marrow stromal cells (MSCs) as evidenced by . . . Prockop” (Ans. 5 and 7).

FF 5. Examiner finds that ‘765 uses the terms “‘Mesenchymal stem cell’ and ‘Marrow stromal cell’ . . . interchangeably” (*id.*).

FF 6. Examiner finds that since Appellant’s Specification does not define the term “homogenous” the term reads on “heterogenous” (e.g., a cell population that is 70, 80, or 90 percent homogenous) (Ans. 13 and 19-20).

ANALYSIS

Appellant contends that neither Nolta nor Wells “teach a homogeneous population of mesenchymal stem cells . . . as claimed” (App. Br. 5 and 15). We agree (*Cf.* FF 3-4). We are not persuaded by Examiner’s assertion that homogeneous means some degree of homogeneity, e.g., heterogeneous (FF 6). The Examiner’s interpretation of the term “homogeneous” would essentially read the term out of the claim, by permitting the presence of cells other than human mesenchymal stem cells. We are also not persuaded by Examiner’s assertion that, despite Appellant’s

disclosure, marrow stromal cells are the same as mesenchymal stem cells because ‘765 uses the terms interchangeably (FF 5; *Cf.* FF 1).

CONCLUSION OF LAW

The preponderance of evidence on this record fails to support Examiner’s finding that Nolta or Wells as evidenced by Prockop and/or ‘765 teaches Appellant’s claimed invention.

The rejection of claims 3-5 under 35 U.S.C. § 102(b) as being anticipated by Nolta as evidenced by Prockop and/or ‘765 is reversed.

The rejection of claims 2, 4, and 5 under 35 U.S.C. § 102(b) as being anticipated by Wells as evidenced by Prockop and/or ‘765 is reversed.

Nolta or Wells in view of Prockop and Caplan:

ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 7. Examiner relies on Nolta and Wells as discussed above (Ans. 9; FF 2-4)

FF 8. Examiner finds that Nolta and Wells fail to suggest “the use of a homogenous population of human mesenchymal stem cells that ha[s] been isolated, purified and then culturally expanded from human mesoderm tissue” or that “the homogenous population of mesenchymal stem cells uniformly express[es] SH2, SH3, and SH4 antigens and lack[s] surface markers for T and B lymphocytes, macrophages, and endothelial cells” (Ans. 10 (emphasis removed)).

FF 9. Examiner finds that Prockop suggests, *inter alia*, “that experiments on the differentiation of MSCs have been carried out [in an attempt] to prepare more homogeneous populations” (Ans. 10 (emphasis removed)).

FF 10. Examiner finds that Caplan suggests “a method of isolating, purifying and . . . expanding human mesenchymal stem cells . . . from bone marrow, including a cell population having greater than 95% of human mesenchymal stem cells that express SH2, SH3 and SH4 antigens” (*id.* at 10-11).

FF 11. Examiner finds that Caplan suggests “monoclonal antibodies specific for human mesenchymal stem cells[] SH2, SH3 and SH4 surface antigens; and that these monoclonal antibodies can . . . be used in the isolation of mesenchymal stem cells through various means” (Ans. 11 (emphasis removed)).

ANALYSIS

Based on the suggestion of Nolte or Wells in combination with Prockop and Caplan, Examiner concludes that, at the time of Appellant’s claimed invention, it would have been *prima facie* obvious to a person of ordinary skill in this art to modify either Nolte or Wells by

using at least a homogenous population of human bone marrow derived mesench[y]mal stem cells expressing uniformly SH2, SH3 and SH4 surface antigens, that has been isolated, purified and culturally expanded to support and/or increase gene transduction for human hematopoietic stem cells in light of the teachings of Prockop and Caplan.

(Ans. 11.) According to Examiner, a person of ordinary skill in this art would have been motivated to modify either Nolte or Wells with the combined teachings of Prockop and Caplan because: (1) Prockop suggested

that the adherent cells used as human stem cell feeder layers have characteristics of bone marrow stromal cells and (2) Caplan suggested a method of isolating and purifying human bone marrow mesenchymal stem cells that express SH2, SH3 and SH4 surface antigens (Ans. 11-12). We are not persuaded. Examiner has failed to explain why, other than through a reliance on hindsight, a person of ordinary skill in this art would have combined Caplan with Prockop to use a specific “homogeneous population of mesenchymal stem cells for co-culturing human hematopoietic cells that are transformed” (*see* App. Br. 27). “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). In this regard, “[c]are must be taken to avoid hindsight reconstruction by using ‘the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.’” *In re NTP, Inc.* 654 F.3d 1279, 1299 (Fed. Cir. 2011).

CONCLUSION OF LAW

The preponderance of evidence on this record fails to support a conclusion of obviousness. The rejection of claims 5 and 7 under 35 U.S.C. § 103(a) as unpatentable over the combination of Nolte or Wells in combination with Prockop and Caplan is reversed.

REVERSED

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